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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/010,246

12/06/2001

Robert Sixto JR.

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27316 7590 05/07/2009
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EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

05/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/010,246	Applicant(s) SIXTO ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 17, 18 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17, 18 and 21-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/30/08 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

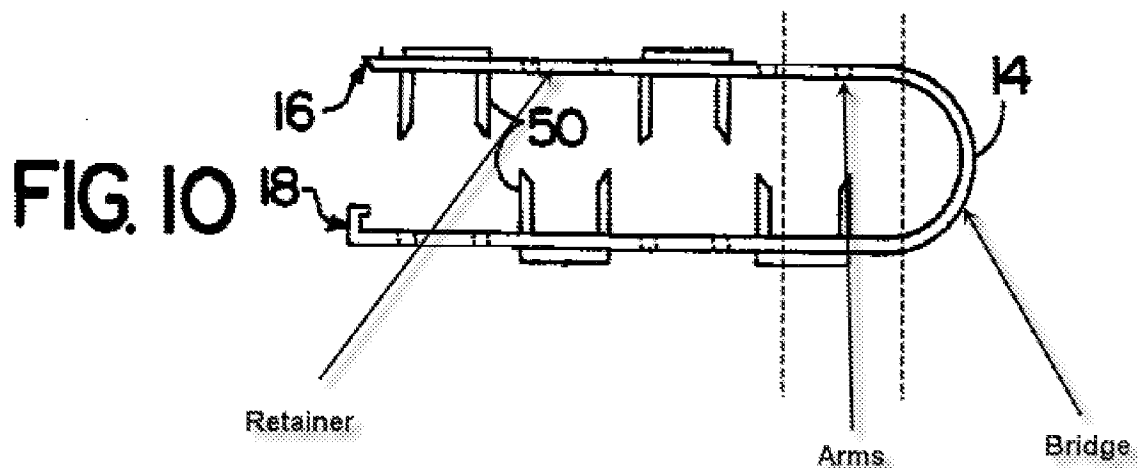
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4, 17, 18, 21-23, 25 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,620,452 to Yoon.

Yoon discloses a surgical clip, as shown in the attached Fig. 10 below, which comprises a first arm; a second arm that is substantially parallel to the first arm; and a bridge connecting said first and second arms to form a substantially U-shaped structure. The arms also include a retainer portion attached thereto capable of penetrating tissue with force. The length of the retainer is fully capable of being at least 3.14 times the distance between the arms when the arms are substantially parallel (depending on how far the hashed line is manipulated). The retainer is also capable of being deformed (Fig. 4). Yoon also discloses the retainer having a tip portion **16** that has a thickness

Art Unit: 3773

smaller than the thickness of the arm; wherein the tip portion **16** is viewed as “sharp” (pointed). The clip of Yoon is also fully capable of retaining its substantially U-shaped configuration prior to, throughout, and subsequent to application (the amount of separation between the two arms merely depends on the amount of force used to press the arms together). The clip is also designed to be used with a clip applier capable of housing multiple clips (col. 3, ll. 41-59).



Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 3773

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 3, 7, 24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon, as applied to the rejections above, and in further view of US 5,222,961 to Nakao et al.

Yoon discloses all the limitations of the claims except for each arm having a retainer that has a sharp tip and the same length. However, the use of such retainers are well known in the art, as taught by Nakao in Figs. 9-12. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the retainer of Nakao in the device of Yoon since it has been held that a simple substitution of one known element for another equivalent element would provide predictable results and involve only routine skill in the art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

6. Claims 5, 6, 8-10, 26, 27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (and in view of Nakao et al.) and in further view of US 4,719,917 to Barrows et al.

Yoon (and Yoon as modified by Nakao) discloses all the limitations of the claims except for the retainer being decouplable from the arms. However, Barrows discloses a similar type of clip/stapling device, wherein the retainer portion of the device is capable of being decoupled from the arms, and wherein the arms have a slot for holding the retainer portion (Fig. 10). This type of arrangement allows for the device to be easily

removed from the patient with minimum discomfort (col. 1, lines 60-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Yoon (Yoon/Nakao) to have decouplable retainers because it would allow the device to be removed from the patient with minimum discomfort.

Response to Arguments

7. Applicant's arguments filed 1/22/09 have been fully considered but they are not persuasive.

The applicant's main argument is directed towards the Yoon reference allegedly failing to disclose a substantially static U-shaped structure retaining the shape prior to, throughout, and subsequent the application of the clip. This is not found persuasive as the shape of the U-shaped structure is merely dependent upon the manipulation of the clip. Fig. 12 of Yoon discloses a clip that has not been applied to a tissue (undeployed). Fig. 13 shows a clip that has been applied to the tissue (deployed), while maintaining the same "U-shaped structure" as shown in Fig. 12.

Note that the claims are directed toward a device-type claim and not a method of applying the clip. Thus, the clip merely has to have the capability of being applied to a tissue while maintaining the original "U-shaped structure" of the undeployed clip. This is shown in Fig. 13 of Yoon since the clip is attached to the tissue via fasteners 40.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773